

REMARKS

This paper is submitted in Response to the Office Action mailed March 11, 2003 for the above-identified application.

In the Office Action, the examined claims, Claims 1-17, were rejected under 35 U.S.C. Sec. 103 for being obvious over U.S. Patent No. 5,580,794 to Allen in view of U.S. Patent No. 5,313,264 to Ivarsson.

The claims were also rejected under 35 U.S.C. Sec. 112 for failing to particularly point out and distinctly claim what the Applicants regard as their invention.

In the Office Action, an objection was also lodged against the present Abstract. A substitute Abstract is now provided under cover of this Response.

Also under cover of this Response, minor changes were made to the specification. The changes do not add new matter.

Before responding to the substantive rejection, there is one additional matter the Applicants now discuss. In the Office Action, it was stated that the relevance of European Patent Publication No. 0 073 980A1 was not considered. As set forth in the Information Disclosure Statement mailed June 18, 2001, the paper under which the '980 Patent Publication was cited, an English language equivalent to the '980 Patent Publication is U.S. Patent No. 4,521,522. Both documents claim priority from German Patent Application No. 3135196 filed September 5, 1983. A copy of the '522 Patent was provided to the Patent and Trademark Office at the time the '980 Patent Publication was cited. The Examiner acknowledged considering the '522 Patent. Therefore, it is believed that the contents of the '980 Patent Publication were considered.

In this Response, Claims 1-17 have been cancelled and new Claims 32-61 are added. Claims 32, 42 and 53 are the independent claims. Claims 33-41 are dependent from Claim 32. Claims 43-52 are dependent from Claim 40. Claims 54-61 are dependent from Claim 53.

Each of the claims particularly points out and distinctly claims the invention to which this application is directed. Therefore, it is respectfully requested that the rejection directed to the failure to meet this statutory requirement be withdrawn.

Allan is merely directed to a disposable assay device. Allan's device includes two "read on" electrodes 26 that are downline of the light sensors. This electrode pair merely "detect[s] movement of the sample liquid beyond the detection zone occupied by the light sensors."<sup>1</sup>

Allen does not suggest the features of Applicants' device as recited by independent Claims 32 and 53 that includes a receiving bracket for removably receiving a test membrane or the cartridge containing the test membrane.

Moreover, as discussed above, in order to determine whether or not a test had been complete, Allen uses his electrodes 26 to monitor the conductivity across a portion of his reagent strip 10. This does not lead one to the feature of Applicant's claimed device wherein, in order to determine whether or not a test is successful, the concentration of light reflected from a control zone is monitored.

If one were to try to use Allan's device repeatedly, it would be necessary to clean the electrodes 26 between uses to ensure that fluids from a first specimen do not give a false indication that a new test has been completed. More importantly, this cleaning would be necessary to ensure that the fluids from the old specimen do not contaminate the new specimen.

Applicants' claimed invention avoids this concern by providing a non-contact method to determine whether or not the assay reactions on the membrane to which a specimen has been applied have run their course.

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<sup>1</sup>U.S. Patent No. 5,580,794, column 8, lines 13-15.

Ivarsson merely teaches a biosensor for performing analysis on fluid flowed through flow channels 14 that are formed in a block 15. There is nothing about this document relevant to the construction of a screening device that, like the claimed assembly, can determine whether or not the light reflected from a membrane control zone indicates if a test was performed and, from the light reflected from the membrane test zone provide an indication of the presence of a compound.

Therefore, Applicants' screening device as recited by Claims 32 and 53 is directed to an assembly that is both beyond the prior art and has benefits not provided by the prior art. Accordingly, these claims are directed to a patentable invention.

Claim 42 is directed to Applicants' method of performing a screening test. In this method, a portion of the concentration of the light reflected from the membrane control zone is determined in order to determine whether or not the test itself was successful.

As discussed above, the prior art does not suggest this type of method. Therefore, it is respectfully submitted that Claim 42 is similarly directed to an invention entitled to patent protection.

The dependent claims are all allowable at least because they depend from allowable independent claims.

Moreover, dependent Claims 41, 52, 55 and 56 are directed to the system and method of this invention, wherein, the processor determines the position of the control zone on the membrane. Based on this information and the photodetector output signals, the processor determines the position of the control zone and, from this data and the detector output signals, the processor determines the concentration of light reflected from the test zone. This feature of the claimed invention ensures that the determination of light reflected from what is supposed to be the test membrane test zone is, in

fact, a true determination of the light reflected from this zone.

This feature of the invention, which is not part of the prior art, ensures that the device and method of this invention compensate for variations in positions of the membranes that are the result of manufacturing tolerances and the inevitable minor positioning variations that occur when the membranes are seated in the device bracket.

Therefore, at least the above-discussed claims are further in condition for allowance because they are independently directed to an assembly that is beyond the prior art.

In conclusion, it is respectfully submitted that the claims, as well as the other parts of this application, are in condition for allowance. Therefore, the Applicants now courteously solicit prompt issuance of a Notice Of Allowance.

Respectfully submitted,

  
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